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TOWNSEND and TOWNSEND and CREW LLP

By: Jessie M. Kelly

Jessie M. Kelly

PATENT

Docket No.: 021305-003900US
Client Ref. No.: 006-140-US33

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mark MATTEUCCI et al.

Patent No.: 7,550,496

Issued: June 23, 2009

Application No.: 10/549,545

Filed: May 26, 2006

For: COMPOSITIONS AND METHODS
FOR TREATING CANCER

Customer No.: 20350

Confirmation No.: 1659

Examiner: Rei Tsang Shiao

Art Unit: 1626

**RENEWED REQUEST FOR
RECONSIDERATION OF PATENT
TERM ADJUSTMENT
DETERMINATION UNDER 37
C.F.R. §1.705(d)**

ATTN: Office of Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This is in response to the December 15, 2009 Decision on Request for
Reconsideration of Patent Term Adjustment under 37 C.F.R. §1.705(d) filed on August
21, 2009, for the above-referenced US Patent. Patentees request that this Renewed
Request be granted based on their rights under the decision of January 7, 2010 by the
United States Court of Appeals for the Federal Circuit see Wyeth v. Kappos Fed. Cir.
2009-1120 (attached); affirming the judgment of the district court in Wyeth et al. v.
Dudas decision (580 F. Supp. 2d 138 (D.D.C. 2008))

Renewed Request for Reconsideration of Patent Term Adjustment

Determination under 37 CFR § 1.705(d).

Pursuant to 37 C.F.R. § 1.705(d), Applicants respectfully request reconsideration of the patent term adjustment determination.

Applicants believe that no fee is required for submission of this Renewed Request. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

In view of the following, it is respectfully requested that Applications be granted a corrected patent term adjustment of **416 days**.

Statement of Facts as Required under 37 C.F.R. §1.705(b)(2)

The correct patent term adjustment is 416 days and not 78 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) mailed on June 3, 2009, with the Issue Notification and listed on the front page of U.S. Patent No. 7,550,496.

The period of adjustment under §1.702(a) is 284 days ("A delay").

The period of adjustment under §1.702(b) is 268 days ("B delay").

The period of adjustment under §1.704(a) is 136 days ("applicant delay").

The period of adjustment under §1.703(f) is 416 days.

The Relevant Dates as Specified in 37 C.F.R. §§1.703(a)-(e), §1.704 and the Adjustment Specified in 37 C.F.R. §1.703(f)

1. §1.703(a)

Applicants are in agreement with the Patent Office's determination of a period of adjustment of 284 days under 37 C.F.R. §1.703(a).

2. §1.703(b)

The Patent Office failed to issue a patent within three years of the actual filing date of the above-referenced application. The period of adjustment under 37 C.F.R. §1.702(b) begins on the day after the date that is three years from the 35 U.S.C. 371(b) filing date of the instant application, September 28, 2008, and ends on June 23, 2009, the date the patent was issued. Thus, the effective period of adjustment under 37 C.F.R. §1.702(b) is 268 days as shown in the table below.

| Filing Date (371(b)) | 3-Year Date | Date Patent Issued | Days over 3 years through Patent Issuance |
|----------------------|--------------------|--------------------|---|
| September 28, 2005 | September 28, 2008 | June 23, 2009 | 268 days |

3. §1.703(c)-(e)

There are no relevant dates as specified under §§1.703(c)-(e).

4. Overlapping periods under §1.703(a)-(e)

Applicants have calculated overlapping periods in accordance with *Wyeth v. Dudas* (88 U.S.P.Q.2d 1538 D.D.C. 2008). Periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) overlap only if they occur on the same calendar day or days (*see Wyeth*). There are no overlapping periods under §1.703 (a)-(e).

5. Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

In the initial Request for Reconsideration of Patent Term Adjustment filed on August 21, 2009, Applicants disputed the calculation by the Patent Office of the period of adjustment under §1.704(a) as a total of 206 days indicated by the attached Patent Term Adjustment History (*see Exhibit A*).

1. Amendment after Notice of Allowance (Rule 312)

According to your Decision of December 15, 2009, we note that you do agree that the Patent Office has incorrectly issued 72 days of application delay for this action. However, you provide a calculation of 3 days of delay; this date being calculated from April 13, 2009 to April 15, 2009. We ask that you please recalculate and make the adjustment of 2 days of applicant delay.

Our calculation of Applicant delay remains as follow: Applicants filed the Amendment after Notice of Allowance on April 13, 2009. The Examiner issued a Response to Amendment under Rule 312 on April 15, 2009. Accordingly, the correct period of adjustment is 2 days and not 3 days as determined by the Patent Office as stated in the table below. (*see* 37 C.F.R 1.704(10)(i)).

| Date of Notice of Allowance | Date of Amendment after Notice of Allowance | Date of Response to Amendment under Rule 312 | Days of adjustment |
|-----------------------------|---|--|--------------------|
| April 4, 2009 | April 13, 2009 | April 15, 2009 | 2 days |

The correct period of adjustment under §1.704(a) is 136 days.

6. **§1.703(f)**

The period of adjustment under 37 C.F.R. §1.702(f) is as follows:

| | |
|----------------------|-----------------|
| Type "A" delay: | 284 days |
| Type "B" delay: | 268 days |
| "A" and "B" overlap: | 0 days |
| Applicant delay: | 136 days |
| <u>Adjusted:</u> | <u>416 days</u> |

Terminal Disclaimer

The instant application is not subject to a terminal disclaimer at this point.

Statement under 37 C.F.R. §1.705(d)

The instant patent issued on June 23, 2009, and Applicants submit their initial request for reconsideration of patent term adjustment on August 21, 2009. This was within the two-month time frame set forth under 37 CFR § 1.705(d).

Remarks regarding the PTO response in view of the Wyeth et al. decision

Pursuant to 35 USC § 154(b)(4)(A), a patentee may pursue civil action in the United States District Court for the District of Columbia (D.D.C.) against the Director if dissatisfied with a determination regarding a Request for Reconsideration of Patent Term Adjustment. In the present case, the statutorily 180 day deadline for filing such a complaint has passed. However, this renewal is filed within the 30 day period set by the Petition Office for this response.

On September 30, 2008, the sole court with jurisdiction to hear a challenge based upon a similar request decided against the interpretation of the PTO regarding §154(b)(2)(A) and, in effect, 37 CFR § 1.703(f) (69 Fed. Reg. 34283 (2004)). Per *Ithaca College v. NLRB*, 635 F.2d 224, 228 (2d Cir. 1980) (citing inter alia *Marbury v. Madison*, 5 U.S. (1 Cranch) 134, 177, 2 L.Ed.60 (1803)), "...it is the courts that have the final word on matters of statutory interpretation," despite any deference given to an agency's interpretation of the statute that it administers.

Patentees submit that the Decision to Dismiss by the PTO, an administrative body, was improper. For this reason, and based upon the recent decision of the United States Court of Appeals for the Federal Circuit, see *Wyeth v. Kappos* Fed. Cir. 2009-1120 (attached) to preserve the right of Patentees to the entire term of U.S. Patent No. 7,550,496, we are submitting this renewed request.

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PATENT

Patentee respectfully request that the PTO reverse its decision, and grant the patentees
Request of 416 days.

Respectfully submitted,



Mark H. Hopkins, Ph.D.
Reg. No. 44,775

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: (925) 472-5000
Fax: (415) 576-0300
M3H:jmk

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